510(k) Summary

truFreeze® System

K113021

FEB - 7 2012

Applicant	CSA Medical
Establishment Registration Number	3004534508
Contact Person	Colleen A. Kistler, RAC tel. 443-524-9688 fax. 866-300-5183 ckistler@csamedical.com
Summary Date	January 23, 2012
Proprietary Name	truFreeze® System
Classification	Class II
Classification Name	Cryosurgical Unit, Cryogenic Surgical Device
Regulation Number	21 CFR 878.4350
Classification Product Code	GEH
Predicate Devices	CryMed Cryo-Ablator (K040809) CryoSpray Ablation System (K060555, K0702651) Mobile Care Monitor (K090138) Smart Wand-DTX System (K093557)

Device Description

The truFreeze® System is a cryosurgical tool that applies medical-grade liquid nitrogen to the ablation area via a small, low pressure, open tipped catheter. The truFreeze System consists of (1) a console and (2) a disposable spray kit.

The console is the central interface of the system and is comprised of a touch panel computer (TPC) and cryogen, suction and electronics modules packaged in a mobile cart. Users interact with the console through a dual foot pedal and the touch panel. A controller and associated software manage the cryogen level sensing, filling, pressure, cooling, defrost, suction, timing and data management functions. A wireless remote control provides alternative timer control from a distance in the procedure room. A fill kit, stored on the rear of the console, allows for liquid nitrogen transfer from the source tank to the console. Safety features include indicators, tank pressure relief valves, an isolated low voltage power system, and an emergency shut-off button.

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The truFreeze spray kit consists of sterile single-use catheters and cryogen decompression tubes (CDTs). The catheter is flexible and capable of retroflex in a scope. The CDT and accessory tubes are included for use with the on-board suction system.

Intended Use/Indications for Use

The truFreeze System is intended for use as a cryosurgical tool for the destruction of unwanted tissue in the fields of dermatology, gynecology and general surgery.

Technical and Operational Characteristics

The truFreeze System is similar in design and has the same operational and technological characteristics as the predicate devices. The minor differences and additional features improve the overall ease of use, robustness and serviceability and do not raise any new issues of safety and effectiveness.

Summary of Testing

The truFreeze System was subjected to a comprehensive test program to evaluate conformance to product specifications and demonstrate substantial equivalence to the predicate device(s). Electrical safety and electromagnetic compatibility testing, software testing, biocompatibility and sterilization testing were conducted in accordance with applicable standards. In addition to the design verification and validation testing, user validations using animal models were also conducted. Test results demonstrated that the truFreeze System meets its specifications and does not raise any new safety and/or effectiveness issues.

Substantial Equivalence

The truFreeze System has the same technological characteristics and principles of operation as the predicate device(s). The minor differences between the truFreeze System and its predicate device do not raise any new issues of safety and effectiveness and therefore is substantially equivalent.

The truFreeze System has the same intended use and indication for use as other legally marketed predicate liquid nitrogen cryosurgical devices and therefore is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

CSA Medical, Incorporated
% Ms. Colleen A. Kistler, RAC
Director, Regulatory & Quality
1101 East 33rd Street, Suite E305
Baltimore, Maryland 21218

FEB - 7 2012

Re: K113021
Trade/Device Name: truFreeze® System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: January 5, 2012
Received: January 6, 2012

Dear Ms. Kistler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K113021

Device Name: truFreeze® System

Indications for Use:

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Prescription Use_____√_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DSR CLIN OP

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113021